UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,113	01/09/2002	Ronald L. Ream	112703-201	9176

29156 7590 12/11/2006

BELL, BOYD & LLOYD LLC
P. O. BOX 1135
CHICAGO, IL 60690-1135

EXAMINER	
HOWARD, SHARON LEE	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,113	REAM ET AL.	
	Examiner	Art Unit	
	Sharon L. Howard	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 9/7/06

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 8-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 8-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Receipt of the Request for Continued Examination and the Petition for Extension of Time filed on 9/7/06 have been acknowledged by the examiner. Applicant's arguments filed on 6/6/06 have fully been considered and are persuasive. The rejection is rendered moot in view of a new grounds of rejection. However, upon further consideration, a new ground of rejection is made in view of Lee (U.S. Patent No. 6,060,078) in view of Hoy et al. (U.S. Patent No. 5,489,436) and further in view of Eisenstadt et al. (U.S. Patent No.5,846,557). Receipt of the Amendment after Final and the Remarks filed on 6/6/06 have been acknowledged and claims 8-20 remain pending in this application.

Claim Objections

Claims 9,11 and 13 are objected to because of the following informalities: It appears that the word "nutaceuticals" is misspelled in claim 9. The correct spelling is "nutraceuticals".

The word "ethyl maltol" has been repeated twice in claim 11. Appropriate correction is required.

In claim 13, the words "chosen from the group consisting of" is improper Markush language. Proper Markush language is "selected from the group consisting of"

DETAILED ACTION

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8-20 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-20 of copending Application No. 09/631,326. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap and they are similar in scope. The copending claims 8-20 of Application No. 09/631,326 and the instant application are both directed to a product comprising a medicament comprising a tableted center and a coating comprising a medicament that surrounds the tableted center, the coating comprising at least 50% by weight of the product, wherein the coating includes a taste masking agent, a high-intensity sweetener and at least one compressible excipient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include dextrose in the claims of '326 in order to obtain the desired result.

This is a provisional obviousness-type double patenting rejection.

Claims 8-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of Ream et al. (U.S. Patent No. 6,355,265 B1) in view of claims 1-11 of Young Won Lee (U.S. Patent No. 6,060,078).

Ream teaches a chewing gum comprising a gum center and a coating which comprises a medicament that surrounds the gum center, the coating comprises at least 50% by weight of the chewing gum product. Ream also discloses 30% to about 99% of a taste masking agent, including a high-intensity sweetener.

Although the reference does teach a gum center, the reference does not teach however a consumable tableted center (emphasis added).

On the otherhand, Lee ('078) does teach a consumable tableted center (see col.2, lines 1-3). Lee teaches a chewable tablet comprising a core (see col.2, lines 1-3) and an outer layer of chewable base, wherein the outer layer may be hard candy or gum. Lee discloses that the chewable base may additionally contain excipients such as sugars (see col.2, lines 33-53).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Ream reference to include a tableted center as taught by the Lee reference. One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to obtain a chewing gum which comprises a tableted gum center and a coating comprising a medicament that surrounds the gum center, a taste masking agent and a high-intensity sweetener.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young Lee (U.S. Patent No. 6,060,078) in view of Hoy et al. (U.S. Patent No. 5,489,436) and further in view of Eisenstadt et al. (U.S. Patent No. 5,846,557).

Lee ('078) teaches a consumable tableted center (see col.2, lines 1-3). Lee teaches a chewable tablet comprising a core (see col.2, lines 1-3) and an outer layer, which defines the coating of chewable base which may be hard candy or gum. Lee discloses that the chewable base may additionally contain excipients such as sugars (see col.2, lines 33-53).

Lee does not particularly teach that the outer layer comprises at least 50% by weight of the product.

However, Hoy discloses that the exact proportions of coating to medicament desired can be determined by routine experimentation (see col.6, lines 57-64). Hoy

further teaches chewable tablets containing means to mask the taste of medicaments or active ingredients (see col.1, lines 10-15). The medicament is coated with about 2 to 55% by weight of the total weight of the coated medicament composition (see col.2, lines 44-62). Hoy discloses acetaminophen, ibuprofen, naproxen, antihistamines, gastrointestinal drugs (e.g. famotidine, loperamide, ranitidine and cimetidine) and decongestants (e.g. pseudoephedrine) (see col.2, lines 44-57).

Eisenstadt is relied on for the teaching of chewing gum compositions comprising a medicament which are known for masking the unpleasant tastes of the medicaments (see col.1, lines 8-12). The reference discloses that the chewing gum compositions include an effective amount of an antitussive agent and a taste masking mixture of a high intensity sweetener, a flavorant and a menthol and that the compositions are capable of delivering an antitussive effect upon chewing substantially without imparting the unpleasant taste (see col.4, lines 1-49). The reference also discloses that the chewing gum compositions can include one or more additional medicaments (see col.4, lines 62-67, col.5, lines 1-35)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Lee reference to include the particular amount of the coating into the Hoy reference and also to include a taste masking agent taught by the Eisenstadt reference. One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to achieve a chewing gum composition comprising a consumable tableted center and a coating comprising a medicament, a high intensity sweetener and a taste masking agent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Howard

Sharon Howard
November 13, 2006

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
11/13/2006